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Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

REPLY BRIEF IN FURTHER SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

Petitioners' Rule 29.6 statements were set forth at page ii of their Petition for a Writ of Certiorari, and there are no amendments to those statements.

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INTRODUCTION

Since the filing of the Petition, the United States Court of Appeals for the Third Circuit has supplied an extra ingredient that makes this case even more cert-worthy: It issued a decision that presents a clear and intractable conflict between a state's highest court and a federal court of appeals on the question presented by the Petition. In *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 251 (3d Cir. 2009), the Third Circuit held that the Vaccine Act categorically preempts all design defect claims. That is the opposite of what the Georgia Supreme Court held in this case. The Third Circuit explicitly considered and rejected the Georgia Supreme Court's analysis of Section 22 of the Vaccine Act. The Third Circuit further explained that the Georgia Supreme Court's construction of Section 22 threatened to destabilize the vaccine market, just as the Petition and the supporting *amicus* briefs argue.

This clear split between a state supreme court and a circuit court—on a question of law that is of critical importance to national public health policy—warrants this Court's review. The issue must be resolved now to prevent the very litigation crisis Congress averted by passing the Vaccine Act.

I. THE THIRD CIRCUIT'S RECENT DECISION CONFLICTS DIRECTLY WITH THE GEORGIA SUPREME COURT'S DECISION BELOW.

The Third Circuit in *Bruesewitz* and the Georgia Supreme Court in this case each confronted the same pure legal question—whether the Vaccine Act

categorically preempts all design defect claims—and came to diametrically opposite conclusions. As in this case, the plaintiffs in *Bruesewitz* argued that the vaccine-related injury could have been avoided by a vaccine design that they contend would have been safer than the one approved by the FDA. *Bruesewitz*, 561 F.3d at 237. The Third Circuit (joining every court outside Georgia) held that the Vaccine Act expressly preempts "all design defect claims." *Id.* at 248; Pet. at 26-27.

The Third Circuit concluded that the statutory text, structure, and legislative history of Section 22 showed "a 'clear and manifest' expression of congressional intent" to preempt design defect claims. *Bruesewitz*, 561 F.3d at 246, 251. The Third Circuit further found that the 1986 House Committee on Energy and Commerce Report supported this conclusion. The Committee Report "repeatedly stressed the importance of vaccine development and availability"; "emphasized that the new system would reduce and stabilize litigation costs"; and "explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims." *Id.* at 248-49.

In so ruling, the Third Circuit rejected the Georgia Supreme Court's analysis, politely noting that it did "not consider the *Ferrari* Court's reading [of Section 22] to be compelling." *Id.* at 246. Contrary to plaintiffs' contention, the unanimous Third Circuit panel did not "express[] doubts about its own analysis" (Opp. at 15) and it certainly did not "effectively adopt[] the product-specific analysis that the Georgia Supreme Court interpreted § 22 to

require." Opp. at 21. The Third Circuit stated that the Georgia Supreme Court's "construction [of Section 22] is contrary to the structure of the Act because it does not bar any design defect claims. If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246. The court further found that "[e]ach of the objectives [of the Vaccine Act] extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute," leading to the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." *Id.* at 249. Specifically, such a construction "would undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs." *Id.*

Contrary to plaintiffs' assertion, this was not "a narrow holding" about only one sort of design defect claim, nor did the Third Circuit express a hint of "ambivalence" about "the scope of § 22." Opp. at 20-21. In advancing these assertions, plaintiffs fixate on a passage that appears after the Third Circuit reached the definitive "*conclusion* that the Vaccine Act preempts *all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added). In that passage, the Third Circuit buttressed—rather than undermined—its conclusion with the observation that "*[e]ven if* Congress did not intend to prohibit all design defect claims against vaccine manufacturers," it plainly "intended to preempt the specific claim at issue" in

that case. *Id.* at 250 (emphasis added). The Third Circuit underscored that this backup argument was no retreat from the broader holding in a summary section immediately after the "even if" discussion:

> [T]he structure and purpose of [Section 22] make clear that Congress intended to preempt some design defect claims. The legislative history identifies the scope of this preemption, which *encompasses both strict liability and negligent design defect claims.*

Id. at 251 (emphasis added).

Plaintiffs are also incorrect that review should wait, on the chance that other courts will reject the Third Circuit's dismissal of subsequent legislative history. Opp. at 17-22. If anything, the dispute over subsequent legislative history highlights the irreconcilable holdings of the Georgia Supreme Court and the Third Circuit. The Georgia Supreme Court afforded the post-enactment legislative statements nearly dispositive weight. *See* App. 13-15. The Third Circuit, however, consistent with other courts, properly gave the statements no weight. *Bruesewitz*, 561 F.3d at 250. The Third Circuit's conclusion is in keeping with this Court's admonition that such subsequent legislative statements are "a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). Further percolation will not reconcile these divergent approaches to subsequent legislative history or provide a path to reconcile *Bruesewitz* with *Ferrari*.

Congress enacted the Vaccine Act to create a uniform national vaccine policy and to impose uniform standards of responsibility on all vaccine manufacturers in all states. Now, with the Georgia Supreme Court's decision, uniformity is gone. A vaccine manufacturer sued under Georgia law is held to a standard of responsibility for design defect and is subject to litigation that is preempted in any federal court in New Jersey, Pennsylvania, and Delaware. This Court should grant certiorari to resolve this split.

II. LITIGATION AGAINST VACCINE MANUFACTURERS POSES A REAL THREAT TO THE NATION'S VACCINE SUPPLY.

Resolution of the split should not await some future case. The uniform view of the public health community (as expressed in an *amicus* brief submitted by the American Academy of Pediatrics and 10 other physician and public health organizations) is that if the decision below is allowed to stand, it "could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country." AAP Br. at 19. In response, plaintiffs offer bland assurance that the Georgia Supreme Court's rule poses "no plausible national vaccine crisis." Opp. at 23 (capitalization omitted). Because betting against the public health community could have disastrous consequences, the Court should reject plaintiffs' assurance unless it is rooted in solid facts and flawless logic. In fact, plaintiffs' assurance depends on three propositions, all of which are wrong.

Plaintiffs' first argument is that "Petitioners exaggerate the increase in vaccine-related court cases." Opp. at 23 (capitalization omitted). "The recent 'spike,'" they assert, "is nothing more than an illusion created by aggregating data from *four* years into a single bar on the graph." *Id.* at 24 (emphasis in original). But disaggregating that one bar does not erase the spike. Assume, as plaintiffs assert, that it is more appropriate to present the data as if there have been "[o]n average . . . 90 lawsuits per year." *Id.* at 24. If so, the number of vaccine cases filed over the decade are as follows: 13, 6, 4, 1, 5, 2, 90, 90, 90, 90. Pet. at 21. Or, compare the four-year period from 1997 to 2000 against the four-year period from 2001 to 2004: The first period saw 12 cases, the latter period saw over 350 cases. *Id.* However the data is cut, that is a dramatic spike.

Plaintiffs' second argument is that "beyond the supposed uptick in civil filings . . . there is no reason to believe that there will be [a further] unmanageable flood of new vaccine-related litigation in state courts." Opp. at 25. Plaintiffs' main support for this proposition is a chart that they assert indicates that "the number of filings *in the Vaccine Court* in recent years is well within normal parameters." Opp. at 25 (emphasis added). The chart, however, shows that in the last eight years, the Vaccine Court has been flooded by claims linking autism to childhood vaccines (i.e., the very theory advanced by plaintiffs in this case): over 5,500 claims were filed during that time compared to 24 in the previous 14 years – a nearly 230-fold increase. The enormous volume of autism cases led the Vaccine Court to create an unprecedented Omnibus

Autism Proceeding to manage the influx of so many new claims. *See In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2002 WL 31696785 (Fed. Cl. July 3, 2002). Of the autism cases reflected on plaintiffs' chart, over 4,900 still remain in Vaccine Court.

In addition to being wrong, plaintiffs' argument misses the point. Whether *Vaccine Court* filings have remained steady in the years before the Georgia Supreme Court issued its opinion has no bearing on whether plaintiffs will be more likely, going forward, to reject the Vaccine Court's rulings and file civil actions. Every vaccine case has to start in the Vaccine Court. The critical point—and the one plaintiffs fail to answer adequately—is that the Georgia Supreme Court's rule will reduce the Vaccine Court to nothing but a base that plaintiffs touch en route to court.

On this point, plaintiffs' position rests on an implausible scenario: "Even if the Vaccine Court finds no causation"—leaving all 4,900 claimants empty-handed– plaintiffs predict that all those claimants might en masse "conclude that they have had their 'day in court'" and refrain from filing actions in courts, which the Georgia Supreme Court has now declared open for business for design defect claims. Opp. at 28. To predict that a significant proportion of these claimants will opt to proceed to another forum after losing in the Vaccine Court is not "sheer speculation." Opp. at 27. It is common sense, rooted in decades of experience with multiple categories of mass tort cases in U.S. courts. Even if half of the claimants call it quits after a loss in the Vaccine Court, that would leave a flood of over 2,400

claims headed to civil courts—and, if the Georgia Supreme Court rule prevails, to trial on a design defect theory.

Finally, plaintiffs argue that the Court should be unconcerned by any potential deluge, because "Congress expressly *preserved* the ability of" plaintiffs to sue in court on claims like these. Opp. at 25 (emphasis in original). But that is the very question presented by this case—one that should be reviewed and considered by this Court. If plaintiffs are wrong—and Congress in fact intended to block the very sorts of design defect claims that triggered the vaccine crisis in the first place—then the prospect of an imminent deluge poses the very threat to public health that Congress sought to prevent.

III. THIS COURT HAS JURISDICTION TO REVIEW THE GEORGIA SUPREME COURT'S DECISION.

As the Petition explains, the Georgia Supreme Court's judgment is reviewable under the fourth category of cases identified in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975). *See* Pet. at 1-2. This case satisfies all three prongs required by that category. Plaintiffs concede the first prong is met, but they contest the other two. They are wrong.

Prong two requires a showing that "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come." *Cox*, 420 U.S. at 482-83. In other words, in order to establish jurisdiction as to any

"relevant cause of action," Petitioners must demonstrate that the "relevant cause of action": (1) survives to proceed to trial under the Georgia Supreme Court's ruling; but (2) would be precluded if Petitioners were to prevail in this Court.

Here, plaintiffs have asserted two distinct design defect causes of action. First, plaintiffs pled a strict liability design defect claim. App. 1. Petitioners argued that this claim is preempted. The Georgia Supreme Court rejected that argument, which means that there *will* be further litigation on the claim, unless this Court intervenes. App. 18. If Petitioners persuade this Court that this claim is preempted, there will be no further litigation on the claim. Plaintiffs do not dispute this.

Second, plaintiffs pled a separate, and wholly distinct, negligent design defect claim. App. 1. This claim is in the same procedural posture as the strict liability claim. Every word of the previous paragraph applies with equal force to this second design defect claim. Plaintiffs do not dispute this, either.

Plaintiffs nevertheless insist that there is no jurisdiction, as to either claim. They assert that it is conceivable that the reversal of the decision below might "not completely preclude [plaintiffs'] design defect claim, but merely dictate [plaintiffs'] burden of proof." Opp. at 14. Specifically, they hypothesize that the Court may ultimately accept the preemption defense as to claim one (strict liability) but reject the preemption defense as to claim two (negligent design). *Id.* at 13-14. Such a split decision is a legal impossibility, for there is no way to read Section 22

to distinguish one sort of design defect claim from another—and no court, on either side of the divide, ever has.

In any event, when plaintiffs refer to different "burden[s] of proof," what they actually mean is that the two alternative claims have different elements. Their jurisdictional argument pretends that this case presents a choice between two evidentiary routes toward proving a singular "design defect claim"—a solitary "underlying cause of action" that could survive in part even if this Court reverses the Georgia Supreme Court. Opp. at 14. Not so. The two claims are distinct causes of action and plaintiffs pleaded them as such. App. 1. When each of the "relevant cause[s] of action" is considered separately, as *Cox* requires, 420 U.S. at 482-83, this Court faces a binary choice: to allow each "relevant cause of action" to proceed (as the Georgia Supreme Court directed) or to reverse and preclude the "relevant cause of action" in its entirety (as Petitioners advocate and as every court outside Georgia has held). If, as Petitioners have demonstrated, the Court would have jurisdiction as to each claim if presented alone, it does not lose jurisdiction just because both claims are in the same case.

That binary choice distinguishes this case from *Nike, Inc. v. Kasky*, 539 U.S. 654 (2003). In *Kasky*, the question was whether Nike's allegedly false statements were protected by the First Amendment. *Id.* at 657. As Justice Stevens's concurrence explains, the Court had to dismiss the case for lack of jurisdiction because there were a number of scenarios in which the Court could reverse the state court without finally disposing of the First

Amendment defense to the plaintiff's claims. *Id.* at 660 (Stevens, J., concurring). That is not the situation here. The only question presented in this case is whether the Vaccine Act categorically preempts all design defect claims. This Court will have no choice but to answer this question definitively if it reviews the Georgia Supreme Court's judgment.

As to prong three, for all the reasons recited above and in the Petition (Pet. at 19-26), and in the *amicus* briefs (AAP Br. at 18-21), plaintiffs are incorrect in disputing that "refusal immediately to review the state court decision might seriously erode federal policy." *Cox Broad. Corp.*, 420 U.S. at 483. The danger is created by the very existence of the Georgia Supreme Court opinion, which will open the floodgates to the litigation deluge that spurred Congress to action in the first place.

Plaintiffs' main argument about this third prong—that "[t]his Court is . . . likely" to address the preemption question "in a future case" (Opp. at 14)—is not at all responsive either to the federal policy or to the emergency. If a flood occurs, later will be too late. In this regard, this case is analogous to *Belknap, Inc. v. Hale*, where this Court found that it had jurisdiction to review the state court judgment because to allow proceedings to continue in state court "without resolving the preemption issue would involve the serious risk of eroding the federal statutory policy of 'requiring the subject matter of respondents' cause to be heard by the . . . [National Labor Relations] Board, not by the state courts.'" 463 U.S. 491, 497 n.5 (1983) (quoting *Cox Broad. Corp.*, 420 U.S. at 483).

Here, the split between the courts can be reduced to a similar forum-related question: Did Congress intend for the Vaccine Court to be the only forum available to claimants alleging that their vaccine-related injury is attributable to the FDA-approved design of the vaccine—or is a civil court also an appropriate forum? Requiring manufacturers to litigate the safety of FDA-approved vaccine designs in courts across the country involves a serious risk of eroding the federal statutory policy to "reduce and stabilize litigation costs" by removing such claims from civil litigation. *Bruesewitz*, 561 F.3d at 249. The determination of this critical threshold issue should not be delayed.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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